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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,447	08/20/2003	Ricky W. Purcell	18189 (27839-2513)	7982
45736 7590 03/02/2011 Christopher M. Goff (27839) ARMSTRONG TEASDALE LLP 7700 Forsyth Boulevard Suite 1800 St. Louis, MO 63105				
EXAMINER				
GHALL, ISIS A D				
ART UNIT		PAPER NUMBER		
1611				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USpatents@armstrongteasdale.com

Office Action Summary

Application No.

10/645,447

Applicant(s)

PURCELL, RICKY W.

Examiner

Isis A. Ghali

Art Unit

1611

**– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 09 February 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-43, 46, 47 and 49-62 is/are pending in the application.
- 4a) Of the above claim(s) 32-39 and 49-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-43, 46 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The receipt is acknowledged of applicant's amendment and request for RCE, both filed 02/09/2011.

Claims 32-43, 46, 47, 49-62 are pending.

Claims 32-39, 49-62 are withdrawn from further consideration as being drawn to nonelected invention. Election was made with traverse in the reply filed on 02/07/2007.

Claims 40-43, 46, and 47 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/09/2011 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 40-43, 46, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Westplate (US 4,592,358, of record) in view of either Zhang et al. (US 6,245,347, of record) or Fischer et al. (US 6,455,066, currently listed on PTO 892), each combination is further in view of either Kanios et al. (US 6,905,016, of record) or Sudsina et al. (US 6,004,345, of record).

Applicant Claims

Applicant's claim 40 is directed to a system for providing therapy to a portion of a body, the system comprising: a container that includes at least one compartment; a first patch held by said container, wherein said first patch is a topical analgesic patch and applies a first analgesic therapy to the portion of the body when said first patch engages the portion of the body; a second patch held by said container, wherein said second patch applies a second therapy to the portion of the body when said second patch

engages the portion of the body, the second therapy being different than the first therapy; and a flexible wrap held by said container, the flexible wrap being adapted to secure at least one of said first patch and said second patch to the portion of the body, wherein the first patch, the second patch and the flexible wrap are all within the same compartment in the container.

Claim 41 is directed to third patch in the container. Claim 42 recites endothermic and exothermic patches. Claim 43 requires enclosure for the patches, and claims 46 and 47 require container or board as a holder. Claim 46 recites more than one first patch in the container. Claim 47 requires releasably attachment of the patches to the holder.

Determination of the Scope and Content of the Prior Art
(MPEP §2141.01)

Westplate teaches therapeutic device (10) to treat injured parts of the body featuring a plurality of compartments (12) enclosing packets (12) containing therapeutic substances which may be a **refrigerant, which reads on endothermic patch, a heat releasing substance, which reads on exothermic patch, and a high density material or weighed packets of high density materials, which reads on third patch**, the device may be wrapped on various body portions using strap means (16) (abstract; col.2, lines 15-19; col.4, lines 20-40; col.5, lines 25-26). The packets slide easily into compartments of the device, which reads on holder as a container (col.3, lines 1-4). Packets reads on patches claimed by applicants because applicant disclosed

patch as "packs, packages, inserts, buttons, and/or any other devices that is readily applied near an injured portion of the body to apply therapy", page 5, lines 11-12 of the present disclosure. The figures show holder that can read on board. The device comprises a plurality of compartments, but any number of compartments may actually be filled with cooling or heating packets or weights for any particular application. The reference teaches that cooling or heating packets are removable, i.e. releasably attached (col.3, lines 6-20). A therapeutic device may be used to cool or heat, simultaneously, two different, but spaced nearby body areas (col.3, lines 26-35). The device is wrapped around the bodily injury by strap means that encircle the therapeutic device (col.5, lines 50-53). The device is flexible, and this implies that the strap is flexible so it can be wrapped around and encircles areas of the body (col.5, lines 1, 10).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

While Westplate desired to treat injured part of the body and teaches three type of patch in the device, however, the reference does not teach analgesic patch as instantly claimed by claim 40.

Although the device taught by Westplate may be considered to be a container having at least one compartment 12, first and second patches/packets 21, and wrap 16, all being held by one device 10, as interpreted by the board in the decision rendered 04/01/2009, however, Westplate does not explicitly teach the patches/packets and the flexible wrap are within a container as instantly claimed by claim 40.

Zhang teaches analgesic patch that can be advantageously administered along with exothermic heating or endothermic cooling means or devices to control the release and absorption of the analgesic according to the patient's need. The cooling or heating device can be applied directly to the skin and can be fixed by tape, adhesive or the like (abstract; col.5, lines 22-26; col.7, lines 35-39; col.8, lines 27-31; col.9, lines 18-31).

Fischer teaches transdermal patch to deliver anesthetic including analgesic to the skin adjacent to the area of discomfort to relief pain without systemic effect. After application, the area may be covered with a covering including a bandage, a plastic film wrap, non-woven or woven coverings which allow for heat and vapor transport allowing for cooling of the treated area, which provides for greater comfort (col.3, lines 3-33; col.5, lines 39-45; col.6, lines 34-38; col.7, lines 39-55).

Kanios teaches a device for stabilizing drugs in patches and transdermal devices prior to use by providing a packaging system for transdermal patches to prevent and control degradation reaction that can result from moisture contamination and environmental factors (abstract; col.4, lines 5-14). The package is in the form of container or box having reusable lid and loaded with multiple patches (figure 2, col.9, lines 42-50; col.10, lines 63-64). Figure 2 shows one compartment container.

Sudsina teaches kit comprising medicinal elements and a wrap, all packaged and stored in one container to be all conveniently available for use together (figure 2, col.3, lines 54-63). Figure 2 shows one compartment container.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide therapeutic device for providing therapy to injured part of the body, wherein the device features a plurality of compartments containing three packets/patches including exothermic packet, endothermic packet, and third packet enclosing a high density material, and a wrap as taught by Westplate, and further add analgesic patch that advantageously accompanied with cooling or heating means as taught by Zhang, or add analgesic patch that can be wrapped to the areas of discomfort as taught by Fischer. One would have been motivated to add the analgesic patch because Westplate desired to treat injured parts of the body that may need analgesia and because Zhang teaches that it is advantageously to administer the analgesic patch along with exothermic heating or endothermic cooling devices to control the release and absorption of the analgesic, or because Fischer teaches that wrapping analgesic patch to the area of discomfort treats pain at that area without undesired systemic effect. One would reasonably expect providing therapeutic device to treat injured part of the body comprising exothermic packet, endothermic packet, and analgesic patch, wherein the device provides relief of the discomfort of the injured area and further provides controlled delivery of analgesic drug from the analgesic patch to relieve the pain and discomfort of the patient without undesired systemic effect.

Further, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide therapeutic device to treat injured part of the body comprising exothermic packet, endothermic packet, and analgesic patch as taught by

the combination of Westplate with either Zhang or Fischer, and enclose the device containing the packets and the wrap in a container as taught by Kanios. One would have been motivated to do so because Kanios teaches that multiple patches can be packaged in one container to prevent and control degradation reaction that can result from moisture contamination and environmental factors. Further one would have been motivated to enclose the device containing the packets and the wrap taught by Westplate combined with either Zhang or Fischer in the container taught by Sudsina because Sudsina teaches that medicinal elements and a wrap can be all packaged and stored in one container to be conveniently available for use together. One would reasonably achieved package for multiple patches providing different therapeutic effects along with a wrap in one container wherein the patches are protected against moisture and environmental factors during storage and conveniently available for use all together when needed.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

5. Claims 40-43, 46, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al. (US 6,554,787, IDS filed 11/15/2004) in view of either Zhang et al. (US 6,245,347, of record) or Fischer et al. (US 6,455,066, currently listed

on PTO 892), each combination is further in view of either Kanios et al. (US 6,905,016, of record) or Sudsina et al. (US 6,004,345, of record).

Applicant Claims

Applicant's claim 40 is directed to a system for providing therapy to a portion of a body, the system comprising: a container that includes at least one compartment; a first patch held by said container, wherein said first patch is a topical analgesic patch and applies a first analgesic therapy to the portion of the body when said first patch engages the portion of the body; a second patch held by said container, wherein said second patch applies a second therapy to the portion of the body when said second patch engages the portion of the body, the second therapy being different than the first therapy; and a flexible wrap held by said container, the flexible wrap being adapted to secure at least one of said first patch and said second patch to the portion of the body, wherein the first patch, the second patch and the flexible wrap are all within the same compartment in the container.

Claim 41 is directed to third patch in the container. Claim 42 recites endothermic and exothermic patches. Claim 43 requires enclosure for the patches, and claims 44 and 45 require container or board as a holder. Claim 46 recites more than one first patch in the container. Claim 47 requires releasably attachment of the patches to the holder.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Griffin teaches a flexible wrap for providing therapy to a body comprising a holder, and a releasably attached therapeutic patch that is held by the holder that applies therapy to a portion of the body (Figures 2 and 8). Holder reads on board. Griffin also teaches that the therapeutic patch is capable of holding a heating or a cooling patch or vibratory elements (col.4, lines 13-47). Griffin also teaches a method of applying therapy to a portion of the body using the flexible wrap (col.3, lines 40-43, 51-53; col.4, lines 14-26, 36-47).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

While Griffin desired to apply therapy to a portion of the body and teaches three type of patch in one device, however, the reference does not teach analgesic patch as instantly claimed by claim 40.

Griffin does not explicitly teach the packets and the flexible wrap are contained within a container as instantly claimed by claim 40.

Zhang teaches analgesic patch that can be advantageously administered along with exothermic heating or endothermic cooling means or devices to control the release and absorption of the analgesic according to the patient's need. The cooling or heating device can be applied directly to the skin and can be fixed by tape, adhesive or the like (abstract; col.5, lines 22-26; col.7, lines 35-39; col.8, lines 27-31; col.9, lines 18-31).

Fischer teaches transdermal patch to deliver anesthetic including analgesic to the skin adjacent to the area of discomfort to relief pain without systemic effect. After

application, the area may be covered with a covering including a bandage, a plastic film wrap, non-woven or woven coverings which allow for heat and vapor transport allowing for cooling of the treated area, which provides for greater comfort (col.3, lines 3-33; col.5, lines 39-45; col.6, lines 34-38; col.7, lines 39-55).

Kanios teaches a device for stabilizing drugs in patches and transdermal devices prior to use by providing a packaging system for transdermal patches to prevent and control degradation reaction that can result from moisture contamination and environmental factors (abstract; col.4, lines 5-14). The package is in the form of container or box having reusable lid and loaded with multiple patches (figure 2, col.9, lines 42-50; col.10, lines 63-64). Figure 2 shows one compartment container.

Sudsina teaches kit comprising medicinal elements and a wrap, all packaged and stored in one container to be all conveniently available for use together (figure 2, col.3, lines 54-63). Figure 2 shows one compartment container.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide device for providing therapy to portion of the body wherein the device features a plurality of compartments containing three patches including heating patch, cooling patch, and third patch that can be vibratory patch, and a flexible wrap as taught by Griffin, and further add analgesic patch that advantageously accompanied with cooling or heating means as taught by Zhang, or analgesic patch that

can be wrapped to the areas of discomfort as taught by Fischer. One would have been motivated to add the analgesic patch because Griffin desired to treat portion of the body that may need analgesia and because Zhang teaches that it is advantageously to administer the analgesic patch along with exothermic heating or endothermic cooling devices to control the release and absorption of the analgesic, or because Fischer teaches that wrapping analgesic patch to the area of discomfort treats pain at that area without undesired systemic effect. One would reasonably expect providing therapeutic device to treat portion of the body comprising heating patch, cooling patch, and analgesic patch, wherein the device provides relief of the discomfort of the portion of the body and further provides controlled delivery of analgesic drug from the analgesic patch to relieve the pain and discomfort of the patient without undesired systemic effect.

Further, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide therapeutic device to treat portion of the body comprising heating patch, cooling patch, and analgesic patch as taught by the combination of Griffin with either Zhang or Fischer, and enclose the device containing the patches and the wrap in a container as taught by Kanios. One would have been motivated to do so because Kanios teaches that multiple patches can be packaged in one container to prevent and control degradation reaction that can result from moisture contamination and environmental factors. Further one would have been motivated to enclose the device containing the patches and the wrap taught by Griffin combined with either Zhang or Fischer in the container taught by Sudsina because Sudsina teaches that medicinal elements and a wrap can be all packaged and stored in one container to

be conveniently available for use together. One would reasonably achieved package for multiple patches providing different therapeutic effects along with a wrap in one container wherein the patches are protected against moisture and environmental factors during storage and conveniently available for use, all together when needed.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

6. Applicant's arguments filed 02/09/2011 have been fully considered but they are not persuasive.

Applicant argues that Westplate is directed to a therapeutic device featuring a plurality of compartments enclosing a various therapeutic substance, however, Westplate does not disclose or suggest placing the packets and the therapeutic device all within the same compartment in a container. Westplate does not teach providing different therapies to the body. The combination of Westplate, Kanios or Sudsina fails to disclose or suggest a system comprising a first patch, a second patch and a flexible wrap all within the same compartment in a container, wherein the second patch and the first patch apply different therapies to the body, as is required in Applicant's claim 40. Instead, the combination of cited references discloses placing a patch and/or packet,

with a single therapy, in a container. The combination of Westplate with Kanios or Sudsina does not teach analgesic patch.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, Westplate teaches therapeutic **device (10) featuring a plurality of packets (12) containing various therapeutic substances which may be a refrigerant, which reads on endothermic patch, a heat releasing substance, which reads on exothermic patch, and a high density material or weighed packets of high density materials, which reads on third patch, the device may be wrapped on various body portions using strap means (16)**. Therefore, multiple therapeutic patches in one device providing different therapies are taught by Westplate. Although the device taught by Westplate may be considered to be a container having at least one compartment 12, first and second patches/packets 21 that provides different therapies, and wrap 16, all being held by one device 10, as interpreted by the board, however, Westplate does not explicitly teach the patches/packets and the flexible wrap are all within the same compartment in a container. Single container is taught by both references Kanios and Sudsina. Therefore, multiple therapies from different patches is taught by Westplate, and inclusion of multiple patches in one container is taught by Kanios and Sudsina, whether the patches having the same or different therapies. In considering the disclosure of the reference, it is proper to take into account not only the

specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rationale to modify or to combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

Regarding the analgesic patch, it is taught by Zhang and Fischer. Combination of Westplate with Zhang or Fischer and further with Kanios or Sudsina teaches the present invention as a whole with all its elements including the three patches, the wrap and the container and the present invention would have been *prima facie* obvious in the meaning of USC 103 (a)..

Applicants argue that the packets of Westplate are individually placed in the compartments, and are not placed in the compartments together, or with a flexible wrap, as the flexible wrap in Westplate is the container. Kanios discloses a packaging system that can have multiple packets in one pouch, the packets all contain a single therapy. Sudsina discloses a vaporizing ointment in the same container as a flexible wrap, again, the vaporizing ointment is a single therapy. No disclosure in Sudsina of a flexible wrap

in the same container with two different therapies, as is required in Applicant's claim 40. Thus, nowhere does either the combination of Westplate and Kanios or the combination of Westplate and Sudsina ever disclose a container that holds a flexible wrap and a first and second patch, wherein the first and second patch provide different therapies to a user of the system, within the same compartment.

In response to this argument, it is argued that multiple therapies are taught by Westplate, and further Westplate teaches inclusion of the multiple therapeutic patches in one wrap. Kanios and Sudsina teach one compartment container containing multiple patches and possibly wrap for convenience to the user. It would have been obvious to one having ordinary skill in the art at the time of the invention to provide therapeutic device featuring a plurality of compartments enclosing packets containing therapeutic substances which may be a refrigerant, a heat releasing, or a high density material, and a wrap as taught by Westplate, and enclose the device containing the packets and the wrap in a container as taught by Kanios. One would have been motivated to do so because Kanios teaches that multiple patches can be packaged in one container to prevent and control degradation reaction that can result from moisture contamination and environmental factors. Further one would have been motivated to enclose the device containing the packets and the wrap taught by Westplate in the container taught by Sudsina because Sudsina teaches that medicinal elements and a wrap can be all packaged and stored in one container to be conveniently available for use together. One would reasonably achieved package for multiple patches providing different therapeutic effects in one container wherein the patches are protected against moisture

and environmental factors during storage and conveniently available for use, all together when needed. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicant argues that Zhang fails to disclose or suggest a system wherein a first patch and a second patch that provide different therapies being held with a flexible wrap within the same compartment in a container. Neither Westplate nor Zhang disclose a container that holds a flexible wrap and a first patch and a second patch with different therapies within the same compartment. Zhang teaches away from having the dermal drug delivery system in a compartment with a heating or cooling mechanism. Zhang expressly teach that the temperature control apparatus and the dermal drug delivery system are preferably stored in separate compartments of the container. As such, why would one having ordinary skill in the art look to place the temperature control apparatus and the dermal drug delivery system of Zhang within the same compartment?

In response to this argument, it is argued that Zhang is relied upon for the solely teaching of analgesic patch and for teaching the combination of endothermic, exothermic and analgesic patch in one device. The container is taught by Kanios and Sudsina. The elements of the present claims are taught by the combination of cited references, which are device comprising three patches or packets including exothermic, endothermic and analgesic patch. The fact that applicant has recognized another

advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Zhang does not teach away from the present invention. Zhang is an analogous art and it is in the field of applicant's endeavor and reasonably pertinent to the particular problem with which the applicant was concerned, which is transdermal drug delivery using heating element. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). The present invention as a whole is taught by the combination of the cited prior art. "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *In re Gurley*, 27 F.3d 551,553 (Fed. Cir. 1994).

It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is

more than the predictable use of prior art elements according to their established functions." In addition, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR INTERNATIONAL CO. v. TELEFLEXINC. ET AL. (2007).

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter as a whole as defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-

0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611